EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., *et al*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	C.A. No. 09-037 (RBK) (JS)
LUPIN LTD., *et al.*,	)	(CONSOLIDATED)
	)	
Defendants.	)	
SHIONOGI PHARMA, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	C.A. No. 10-135 (RBK) (JS)
MYLAN INC., *et al.*,	)	
	)	
Defendants.	)	

SHIONOGI'S FOURTH SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS TO LUPIN DEFENDANTS (NOS. 82-89)

Pursuant to Rules 34 and 26 of the Federal Rules of Civil Procedure, and the applicable Local Rules of the United States District Court for the District of Delaware ("Local Civil Rules"), Plaintiff Shionogi Pharma, Inc. ("Shionogi") requests that Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin") produce the following documents and things for inspection and copying. Unless otherwise agreed, production is to be made on or within thirty (30) days at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 399 Park Avenue, New York, NY 10022.

DEFINITIONS

1. Any reference to a business entity includes all entities and persons acting on the business entity's behalf as well as all affiliates, divisions, parents, subsidiaries, and predecessors and successors thereof.

2. Any term defined in the singular also includes the plural and vice versa.

3. The terms "and" and "or" shall be interpreted liberally as conjunctive, disjunctive, or both so that the fullest disclosure of information is achieved.

4. The term "concerning" means in any way, directly or indirectly, regarding, considering, constituting, covering, defining, describing, involving, underlying, modifying, amending, confirming, mentioning, endorsing, recording, evidencing, pertaining to, referring to, reflecting, relating to, representing, supporting, qualifying, terminating, revoking, canceling, negating, or having any connection with the matter discussed.

5. The term "document" means each and every writing, whether an original, a draft, or a copy, however produced or reproduced, and each and every thing from which information can be processed or transcribed, and includes, without limitation, all things meeting the definitions of "writings" and "recordings" as set forth in Fed. R. Evid. 1001. Any document without any marks such as initials, comments, or notations of any kind is not deemed to be identical to one without such marks and is to be produced and identified as a separate document. The term "document" is coextensive in scope with Rule 34 of the Federal Rules of Civil Procedure.

6. The term "communication" refers to all conversations, agreements, inquiries, or replies, whether in person, by telephone, in writing, or by means of electronic transmittal devices, and includes, but is not limited to, all correspondence, transmittal slips, memoranda, or notes.

7. The term "thing" means any physical specimen or other tangible item other than a document.

8. The term "person" or "persons" means any natural person or business, legal, or governmental entity or association.

9. The term "identify," when referring to documents, means to provide, to the extent known: the type of document; general subject matter; date of the document; author(s); addressee(s); and recipient(s).

10. The term "identify," when referring to persons, means to provide, to the extent known, the person's full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment. Once a person has been identified in accordance with this paragraph, only the name of that person need be listed in response to any subsequent discovery request seeking such identification.

11. The term "drug product" has the meaning set forth in 35 U.S.C. § 156(f)(2).

12. The term "ANDA" means Abbreviated New Drug Application.

13. The term "Mylan" means Mylan Inc. and Mylan Pharmaceuticals Inc., and each of their respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries (including but not limited to Matrix Laboratories Limited), affiliates, predecessors, and successors.

14. The term "Matrix" means Matrix Laboratories Limited, and each of its respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors, and successors.

15. The term "Lupin" means Lupin Ltd. and Lupin Pharmaceuticals, Inc., and each of their respective officers, directors, representatives, employees, agents, partners, corporate

parents, subsidiaries, affiliates, predecessors, and successors.

16. The term "Lupin's ANDA" means ANDA No. 90-692.

17. The term "Lupin's ANDA Metformin Products" means the metformin products that are the subject of Lupin's ANDA including the metformin products which were shipped and/or sold by Lupin on or around September 30, 2011, and any subsequent importation and sale.

INSTRUCTIONS

1. These discovery requests shall be deemed continuing, requiring Lupin to serve supplemental answers and documents and things promptly in accordance with Rule 26 of the Federal Rules of Civil Procedure. Such documents and things are to be produced as soon as is reasonably possible after they are located or obtained.

2. If Lupin has any good faith objections to any request or any part thereof, the specific nature of the objection and whether it applies to the entire request or to a part of the request shall be stated. If there is an objection to any part of a request, then the part objected to should be identified and documents responsive to the remaining unobjectionable part should be produced.

3. If Lupin withholds information on the grounds of privilege (including work product immunity), Lupin must identify the nature of the privilege which is being claimed and, if the privilege is governed by state law, indicate the state's privilege rule being invoked; and must provide: (i) the type of document, *e.g.*, letter or memorandum; (ii) the general subject matter of the document; (iii) the date of the document; and (iv) such other information as is sufficient to identify the document, including, where appropriate, the author of the document, the addressees of the document, and any other recipients shown in the document, and, where not apparent, the relationship of the author, addressees, and recipients to each other.

4. If Lupin contends that information responsive to any discovery request is

incomplete, then it must provide all responsive information of which it is now aware.

5. Each request shall be answered on the basis of Lupin's entire knowledge, from all sources, after a reasonable and good faith inquiry has been made and a search has been conducted.

6. For any document requested herein that has been destroyed, transferred or lost, Lupin shall identify the document and provide a brief explanation of the circumstances *(e.g.,* when, how, by whom, and why) surrounding the document's destruction, transfer or loss, and any and all records pertaining to its destruction, transfer or loss.

7. If Lupin or its attorneys know of the existence, past or present, of any document or thing called for in a request, but such document or thing is not presently in Lupin's possession, custody, or control or in the possession, custody, or control of its agents, representatives, or attorneys, Lupin shall so state in response to the request, identify such document or thing in response to the request, and identify the individual in whose possession, custody, or control the document or thing was last known to reside.

8. If documents and things are produced as they are maintained in the normal course of business:

b. all associated file labels, file headings thereon, and file folders shall be produced together with the responsive documents from each file;

c. all documents containing markings thereon that cannot be legibly or accurately copied shall be produced in their original form; otherwise, Lupin may produce photocopies; and

d. each page shall be given a discrete production number.

REQUESTS FOR PRODUCTION

REQUEST NO. 83:

All documents, including communications, concerning any U.S. or foreign patent or patent application filed by or on behalf of Lupin relating to controlled or extended release dosage forms comprising metformin or any other biguanide, including the (a) prosecution histories of the patent, and the continuations, continuation-in-part, divisions, reexaminations, and reissues thereof, (b) drafts of the applications and any other document filed in the foregoing applications, (c) documents reflecting disclosures to or communications with any patent attorney, agent or liaison, and (d) documents prepared by or reflecting communications with every other person who was substantively involved in the preparation or prosecution of the applications.

REQUEST NO. 84:

All documents, including communications, concerning any U.S. or foreign patent or patent application filed by or on behalf of Lupin concerning controlled or extended release dosage forms comprising semi-permeable or permeable membranes, including the (a) prosecution histories of the patent, and the continuations, continuation-in-part, divisions, reexaminations, and reissues thereof, (b) drafts of the applications and any other document filed in the foregoing applications, (c) documents reflecting disclosures to or communications with any patent attorney, agent or liaison, and (d) documents prepared by or reflecting communications with every other person who was substantively involved in the preparation or prosecution of the applications.

REQUEST NO. 85:

All documents, including communications, concerning any U.S. or foreign patent or patent application filed by or on behalf of Lupin relating to time to maximum concentration of metformin, including the (a) prosecution histories of the patent, and the continuations,

continuation-in-part, divisions, reexaminations, and reissues thereof, (b) drafts of the applications and any other document filed in the foregoing applications, (c) documents reflecting disclosures to or communications with any patent attorney, agent or liaison, and (d) documents prepared by or reflecting communications with every other person who was substantively involved in the preparation or prosecution of the applications.

REQUEST NO. 86:

All documents, including communications, concerning any U.S. or foreign patent or patent application filed by or on behalf of Lupin describing or exemplifying the product that is the subject of Lupin's ANDA, including the (a) prosecution histories of the patent, and the continuations, continuation-in-part, divisions, reexaminations, and reissues thereof, (b) drafts of the applications and any other document filed in the foregoing applications, (c) documents reflecting disclosures to or communications with any patent attorney, agent or liaison, and (d) documents prepared by or reflecting communications with every other person who was substantively involved in the preparation or prosecution of the applications.

REQUEST NO. 87:

All documents, including communications, concerning any U.S. or foreign patent or patent application filed by or on behalf of Lupin constituting or claiming priority to Indian Patent Application No. 213/KOL/2008, including the (a) prosecution histories of the patent, and the continuations, continuation-in-part, divisions, reexaminations, and reissues thereof, (b) drafts of the applications and any other document filed in the foregoing applications, (c) documents reflecting disclosures to or communications with any patent attorney, agent or liaison, and (d) documents prepared by or reflecting communications with every other person who was substantively involved in the preparation or prosecution of the applications.

REQUEST NO. 88:

All settlement agreements or licensing agreements between Lupin and third parties concerning biguanides, pharmaceutical products indicated for the treatment of diabetes, or pharmaceutical products with extended release characteristics, including without limitation Lupin's settlement and/or licensing agreement with DepoMed Inc. concerning Glumetza®.

REQUEST NO. 89:

All documents and communications concerning or associated with the agreements described in Request No. 88, including without limitation all negotiations, forecasts, and analyses.

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October 5, 2012
6503637

CERTIFICATE OF SERVICE

I hereby certify that on October 5, 2012, copies of the foregoing were caused to be served upon the following in the manner indicated:

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VIA ELECTRONIC MAIL

/s/ Jennifer Ying
_____
Jennifer Ying (#5550)

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., et al., Plaintiffs v. LUPIN LTD., et al., Defendants	)	C.A. No. 09-037 (RBK)(JS) CONSOLIDATED
SHIONOGI PHARMA, INC., et al., Plaintiffs v. MYLAN, INC., et al., Defendants	)	C.A. No. 10-135 (RBK) (JS)

DECLARATION OF CHRISTOPHER P. GERARDI
IN SUPPORT OF SHIONOGI'S MOTION TO COMPEL ADDITIONAL PRODUCTION

I, CHRISTOPHER P. GERARDI, declare and state as follows:

1. I submitted declarations in the above-captioned matters on March 30, 2012 (D.I. 389, Ex. F) and on May 1, 2012 (D.I. 426). In those instances, I was asked by counsel for Shionogi to prepare declarations stating why and how certain types of documents requested by Shionogi are relevant for Shionogi and Lupin to properly consider the type and quantum of economic damages that may be due should Shionogi prevail on its claims.[1]

[1] Declaration of Christopher P. Gerardi, March 30, 2012 ("Gerardi March Declaration") and Declaration of Christopher P. Gerardi, May 1, 2012 ("Gerardi May Declaration"). My *curriculum vitae* is attached as Appendix A to the Gerardi March Declaration.

2. I am now asked by counsel for Shionogi to review "Shionogi's Fourth Set of Requests for the Production of Documents and Things to Lupin Defendants (Nos. 82-89)"[2] concerning additional documents requested by Shionogi and to specify in detail the reasons why Lupin's license agreements and relevant supporting documentation are relevant and appropriate for the purposes of my damages analysis.

3. As discussed in the Gerardi March Declaration at ¶ 15, the assessment of an appropriate reasonable royalty at a hypothetical negotiation between Shionogi and Lupin would, according to my understanding of relevant case law, include an assessment of comparable and relevant licenses (and related negotiation documents) entered into by either Shionogi or by Lupin for comparable or related technology. Licenses, whether in settlement of litigation, or other arms-length and market-based agreements, and related supporting documentation, can provide an understanding of the value of comparable inventions, and also an understanding of a party's expectations related to sales, profits and industry growth. They are therefore probative of the outcome of a hypothetical negotiation (here, between Shionogi and Lupin).

4. I understand that Lupin and Mr. Hofmann previously asserted that "Lupin has no licensing agreements with respect to the metformin hydrochloride extended release product so nothing exists to be produced." (Hofmann Declaration at 37). However, I understand that on or about February 22, 2012,[3] Lupin entered into a settlement and license agreement with Depomed Inc. ("Depomed") concerning Lupin's generic version of Glumetza®, a metformin hydrochloride extended release product (the "Depomed/Lupin Agreement"). Thus, contrary to Mr. Hofmann's earlier claim, it now appears that Lupin has at least one patent license

[2] On October 5, 2012, Shionogi submitted the following request for production: "All settlement agreements or licensing agreements between Lupin and third parties concerning biguanides, pharmaceutical products indicated for the treatment of diabetes, or pharmaceutical products with extended release characteristics, including without limitation Lupin's settlement and/or licensing agreement with DepoMed Inc. concerning Glumetza®." Further, Shionogi requested "[a]ll documents and communications concerning or associated with the agreements … including without limitation all negotiations, forecasts, and analyses." *See* Shionogi's Fourth Set of Requests for the Production of Documents and Things to Lupin Defendants (Nos. 82-89) (attached as Ex. A to Shionogi's December 12, 2012 Letter to the Court).

[3] http://ir.santarus.com/releasedetail.cfm?releaseid=650684.

agreement concerning a metformin hydrochloride extended release product. Further, as discussed in the Gerardi May Declaration, Mr. Hofmann has indicated that Lupin has had discussions with at least one other generic company regarding the potential sale of Lupin's ANDA for metformin hydrochloride extended release as well as a number of other products. (Gerardi May Declaration at 7)

5. It is my opinion that the Depomed/Lupin Agreement and related documents, including documents related to settlement negotiations, would be relevant in evaluating an appropriate reasonable royalty. Further, it is also my opinion that the production of patent licenses (including settlement agreements, as well as supporting negotiation documents and analyses) between Lupin and third parties concerning biguanides, pharmaceutical products indicated for the treatment of diabetes, and extended-release pharmaceutical technology are also likely to lead to discovery of evidence that should be considered in evaluating an appropriate reasonable royalty. The production of such documents is proper for at least the following reasons:

    a. First, the production of such agreements and associated negotiations is directly relevant to several factors under the *Georgia-Pacific v. United States Plywood Corp* ("*Georgia-Pacific*") framework:

        i. In particular, *Georgia-Pacific* factor 2 considers "rates paid by the licensee for the use of other patents comparable to the patent in suit." Here, it is my opinion that the consideration of this factor should include patent licenses concerning:

            1. *Other extended release metformin products, including the Depomed/Lupin Agreement*. Because they would concern the same active ingredient (metformin) and similar technology (extended-release pharmaceuticals), these documents would be relevant evidence that I would want to consider as part of the royalty determination because they would involve comparable patents to those in suit.

2. *Other biguanides products.* Metformin is a member of the class of chemical compounds known as biguanides. I understand that certain patent claims of the patents in suit are directed to extended-release formulations containing a biguanide compound.[4] Therefore, at least for this reason, this category of license agreements comprises agreements concerning other patents comparable to those in suit that an expert would want to reasonably consult in accordance with *Georgia-Pacific* in considering the hypothetical negotiation and royalty determination.

3. *Other drugs for the treatment of diabetes.* I understand that the product in this case, Fortamet®, is a diabetes treatment drug. Therefore, patent licenses entered into by Lupin for other diabetes drugs likely concern comparable patents to those in suit that should also be consulted by an expert in considering the hypothetical negotiation and royalty determination,.

4. *Other extended-release pharmaceutical technology*. I understand that the patents in suit concern extended-release pharmaceutical technology. Accordingly, licenses to other patents for similar technology are likely to yield information concerning the value attributed by Lupin and others to such patents, and an expert would reasonably want to consider these agreements in formulating his or her opinion.

ii. Such agreements and related negotiation documents are relevant to understanding Lupin's approach in evaluating the structure and economics of a comparable license agreement (in this case, with Shionogi), the value Lupin has placed on comparable inventions, and whether these transactions are

[4] *See, e.g.*, United States Patent No. 6,866,866, claims 1 and 25; United States Patent No. 6,099,859, Claim 3.

probative of the royalty rate that would be determined in this matter between Shionogi and Lupin.

iii. Further, *Georgia-Pacific* factor 12 considers "the portion of the profit or selling price that may be customary in the particular business or in comparable businesses." To the extent that the Lupin agreements relate to these subject matters, then the consideration detailed in such agreements may reflect "customary" royalty rates for similar technology in this industry, and therefore may be probative of the reasonable royalty rate that would be determined in this matter between Shionogi and Lupin.

b. Second, the production of such Lupin agreements, specifically settlement agreements, is relevant and appropriate under governing case law:

i. I understand that in *ResQnet.com, Inc. v. Lansa, Inc.,* 594 F. 3d 860 (Fed. Cir. 2010), and *Lucent Technologies, Inc. v. Gateway, Inc.,* 580 F.3d 1301 (Fed. Cir. 2009), the Court of Appeals for the Federal Circuit recognized that settlement agreements may be relevant to a reasonable royalty sought as compensation for patent infringement. Specifically, I understand that settlement agreements are admissible as evidence of a reasonable royalty rate if "sufficiently comparable to the hypothetical license at issue in suit." In the current matter, it is possible that agreements such as the Depomed/Lupin Agreement are the only agreements that may reflect a transaction between Lupin and another party for patents similar to the patented technology and products. Indeed, in the context of license agreements between innovator pharmaceutical companies (here, Plaintiffs) and generic companies (Lupin), it is my understanding that most, if not virtually all, patent license agreements occur in settlement of litigation or threatened litigation.

ii. I understand that case law also supports the production of underlying settlement negotiations.[5] Such additional production is likely to lead to the discovery of probative evidence for the purposes of determining whether the settlement agreements involve similar technology or technology in the same or similar industry, whether the relationship of the licensor and licensee is comparable to that in the current litigation, and the terms of the settlements and what economic considerations factor into a reasonable royalty determination, among others. Such information is also useful for determining whether the agreements accurately reflect a comparable invention's value, or were influenced by other factors, and whether consideration for such value is probative of the royalty rate that would be negotiated between Shionogi and Lupin.

c. Third, the production of such Lupin agreements, specifically including the Depomed/Lupin Agreement, relates to a potentially economically comparable transaction:

i. It is my understanding that the Depomed/Lupin Agreement involves a product launch that may involve a similar economic situation—Depomed's Glumetza®, a branded metformin extended HCL product, and Lupin's ANDA product, a generic metformin extended HCL version of Glumetza®.

ii. If available, relevant documents supporting that settlement, such as Lupin's expected share of the market, Glumetza®'s profits margins, and Lupin's

[5] For example, in *Automated Merchandising Systems Inc. v. Crane Co.*, the Court granted a motion to compel production of "[a]ll documents comprising, concerning and/or relating to" plaintiff's licensing of its own or third-party patents, and "[a]ll documents that bear upon or relate to the issue of what would constitute a reasonable royalty for a license voluntarily taken by [plaintiff] under the [patents in issue]," finding that the Federal Circuit in *ResQNet* "seemed to indicate that these should be discoverable so that parties can establish a factual basis for a reasonable royalty." 279 F.R.D. 366, 372-73 (N.D.W.Va. Oct. 21, 2011). Likewise in *MSTG, Inc., v. AT&T Mobility LLC*, the Court ordered the production of settlement negotiations and communications, finding that "[d]ocuments related to negotiations could shed light on why the parties reached their royalty agreement and could provide guidance on whether some or all of the licenses could be considered a basis for calculating a reasonable royalty." 2011 WL 841437, at *3 (N.D.Ill. Mar. 8, 2011), *aff'd* 675 F.3d 1337 at 1348 (Fed. Cir. 2012).

expected profit margins, may be instructive given that the settlement involves a similarly situated launch of a competing product.

iii. The Depomed/Lupin Agreement likely involves comparable subject matter. Both Glumetza® and Fortamet® are extended release metformin products. I also understand that the patents listed in the "Orange Book" for Glumetza® also concern extended release pharmaceutical technology.

6. At a minimum, experts such as I would want to examine each of the categories of documents discussed above, in order to determine whether, in our opinion, the licenses and related documentation concern "the use of other patents comparable to the patent in suit" (*Georgia-Pacific* factor 2) and/or "the portion of the profit or selling price that is may be customary in the particular business or in comparable businesses" (*Georgia-Pacific* factor 12), and would thus inform our opinions in this matter. The only way to properly consider *Georgia-Pacific* factors 2 and 12 is if such documents are produced.

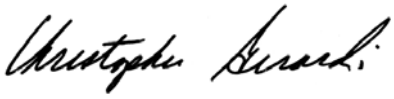
7. In my experience, documents such as the categories of documents discussed above are typically produced in patent litigation in which the reasonable royalty determination is at issue. Although there may be disputes between experts as to whether a particular license agreement concerns "the use of patents comparable to the patent in suit" or a "customary" portion of profit or selling price, in my experience, such disputes concern the weight of the evidence and the expert opinion, as well as perhaps the ultimate admissibility of the evidence. They do not, however, concern the discoverability of documents.

8. In my experience, experts may differ on whether a particular license agreement is relevant to their consideration under *Georgia-Pacific* factors 2 and/or 12. Experts such as myself are frequently cross-examined not only concerning the licenses underlying their opinion, but also as to why they did not consider a particular agreement as relevant to their opinion under *Georgia-Pacific* factors 2 and 12. In my experience, I frequently am called upon to explain why I did or did not include a particular license agreement, or category of agreement, in my royalty calculus. It is self-explanatory that the only way for an expert to make this determination, or for a party to cross-examine an expert on the failure to include or consider a particular license, is for the universe of potentially probative agreements to be produced.

9. My analysis may consider other financial and economic factors not identified in this declaration, or information that may hereafter become available. To the extent additional information is relevant, I reserve the right to supplement, amend, or alter this declaration, as necessary.

10. I declare under penalty of perjury, and in accordance with 28 U.S.C. § 1746, that the foregoing is true and correct to the best of my knowledge and belief.

Executed on December 12, 2012, in New York, New York



CHRISTOPHER P. GERARDI